

## 1. Name of the Medicinal Product

- (a) Product Name : FEXOGESIC OIL  
(b) Pharmaceutical Dosage Form : OIL

## 2. Quality and Quantitative Composition

(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

### Composition:

Diclofenac Diethylamine	BP	2% w/v
Peppermint Oil		10% v/v
Turpentine Oil	BP	10% v/v
Methyl Salicylate	BP	10% v/v
Eucalyptus Oil	USP	10% v/v
Benzyl Alcohol	BP	1% v/v
Oil base		q.s.

(b) Quantitative Declaration, the quantity of the active substance must be expressed per dosage unit

Sr. No.	Name of the Materials	Specification	Label Claim
1.	Diclofenac Diethylamine	BP	20 mg
2.	Peppermint Oil	IHS	100 mg
3.	Turpentine Oil	BP	100 mg
4.	Methyl Salicylate	BP	100 mg
5.	Eucalyptus Oil	USP	100 mg
6.	Benzyl alcohol	BP	10 mg
7.	Heavy Liquid Paraffin	BP	570 mg

**3. Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g.:** An orange color oil packed in white color HDPE Bottle with printed sticker label.

## 4. Clinical Particulars

### 4.1 Therapeutic Indications:

FEXOGESIC OIL is used to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles. It relieves rheumatic and muscular pain, and reduces swelling and inflammation, e.g., in injuries involving the tendons, ligaments, muscles and joints. For the relief of sprains, strains or bruises, backache, tendinitis (e.g., tennis elbow), and for localized and mild arthritis.

## **4.2 Posology and method of administration:**

Adults and Adolescents over 14 years of age: FEXOGESIC OIL should be applied 3- 4 times daily to the affected sites and gently rubbed. Duration of treatment depend on the indication and the patient's response. It is advisable to review the treatment after 2 weeks.

Children and adolescents aged below 14 years

There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age.

Hepatic and renal impairment

No dosage adjustment is required in patients with hepatic impairment.

FEXOGESIC OIL is contraindicated in patients with renal impairment.

Elderly

The usual adult dosage may be used.

Method of administration

Cutaneous use.

Apply on healthy skin only.

After application, the hands should be washed, unless these are being treated.

## **4.3 Contraindications:**

Hypersensitivity to the active substance or to any of the excipients in the oil as listed in section 6.1

Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents (NSAIDs).

The use in children and adolescents aged less than 14 years is contraindicated.

Third trimester of pregnancy.

Patients with renal impairment.

## **4.4 Special warning and precautions for use:**

FEXOGESIC OIL should be applied only to intact skin and or open wounds. It should not come into contact with the eyes or mucous membranes.

## **4.5 Interaction with other medicinal products and other forms of interactions:**

Systemic absorption of FEXOGESIC OIL is low and hence the risk of an interaction is small. No drugs interactions have been reported with FEXOGESIC OIL to date

#### **4.6 Pregnancy and lactation:**

Not applicable

#### **4.7 Effects on ability to drive and use machine:**

No studies on the effects on the ability to drive and use machines have been performed.

#### **4.8 Undesirable effects:**

Occasional skin rash, itching and redness of the skin

#### **4.9 Overdose:**

There has been no experience of overdose with FEXOGESIC OIL

### **5. Pharmacological Properties**

#### **5.1 Pharmacodynamic Properties:**

Non-steroidal Anti-inflammatory and Analgesic Diclofenac is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Diclofenac is a potent non-steroidal anti-inflammatory drug with analgesic and antipyretic properties. It is also having some uricosuric effect. Diclofenac inhibits cyclooxygenase activity with a reduction of production of prostaglandins in the tissue. Linseed oil inhibits PGE2, leukotriene, histamine and bradykinin induce inflammation. The oil also inhibited arachidonic acid-induced inflammation, suggesting its capacity to inhibit both cyclooxygenase and lipoxygenase pathway of arachidonate metabolism. Methyl salicylate is applied topically as counter irritants for relief of pain associated with lumbago, sciatica, and rheumatic conditions.

#### **5.2 Pharmacokinetic Properties:**

When FEXOGESIC OIL is applied locally, the active substances are absorbed through the skin, determined by reference to the urinary excretion of Diclofenac and its hydroxylated metabolites. After topical administration of FEXOGESIC OIL to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid.

#### **5.3 Preclinical Safety Data:**

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity carcinogenic potential and reproductive toxicity, at the intended therapeutic doses.

At high systemic levels of diclofenac, not observed following topical application of FEXOGESIC OIL, toxicity of diclofenac took the form mainly of lesions and ulcers in the gastro-intestinal tract. Increased duration of gestation, dystocia and increased resorptions were observed at maternally toxic doses.

## **6 Pharmaceutical Particulars**

### **6.1 List of excipients:**

Benzyl alcohol  
Heavy Liquid Paraffin

### **6.2 Incompatibilities:**

None

### **6.3 Shelf life:**

60 Months

### **6.4 Special precautions for storage:**

Store below 30°C. Protect from light & moisture.

### **6.5 Nature and contents of container:**

White Color 60 mL HDPE Bottle

### **6.6 Special precaution for disposal:**

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7. Marketing Authorization Holder**

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